



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,444	01/07/2002	Alessandro Moretta	1721-44	6065

23117 7590 10/07/2003

NIXON & VANDERHYE, PC
1100 N GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201-4714

EXAMINER

HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
----------	--------------

1644

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/036,444	Applicant(s) MORETTA ET AL.	
	Examiner Phuong Huynh	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/19/03; 6/6/02; 1/7/02; .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 22-59 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

- I. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.
- II. Claims 22-59 are pending.

Election/Restrictions

- III. Restriction to one of the following inventions is required under 35 U.S.C. 121:
1. Claims 22-38, 41-42, 45-46, 48-49, 51-52 and 57, drawn to an antigen-binding composition comprising an **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 2**, a kit comprising said antibody and further comprises antibody anti-NKp46 or anti-NKp44, a pharmaceutical composition comprising said **antibody**, classified in Class 424, subclass 130.1.
 2. Claims 22, 24-38, 41-42, 45-46, 48-49, 51-52 and 57, drawn to an antigen-binding composition comprising an **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 4**, a kit and a pharmaceutical composition comprising said antibody and further comprises antibody anti-NKp46 or anti-NKp44, classified in Class 424, subclass 130.1.
 3. Claims 22, 24-38, 41-42, 45-46, 48-49, 51-52 and 57, drawn to an antigen-binding composition comprising an **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 5**, a kit comprising said antibody and further comprises antibody anti-NKp46 or anti-NKp44, a pharmaceutical composition comprising said **antibody**, classified in Class 424, subclass 130.1.
 4. Claims 22, 24-38, 41-42, 45-46, 48-49, 51-52 and 57, drawn to an antigen-binding composition comprising an **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 6**, a kit comprising said antibody and further comprises

antibody anti-NKp46 or anti-NKp44, a pharmaceutical composition comprising said antibody, classified in Class 424, subclass 130.1.

5. Claims 22, 24-38, 41-42, 45-46, 48-49, 51-52 and 57, drawn to an antigen-binding composition comprising an **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 7**, a kit comprising said antibody and further comprises antibody anti-NKp46 or anti-NKp44, a pharmaceutical composition comprising said antibody, classified in Class 424, subclass 130.1.
6. Claim 39, drawn to a bispecific binding composition comprising an antigen-binding composition comprising an **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 2** and another **antibody that binds specifically to a specific tumor antigen**, classified in Class 424, subclass 130.1.
7. Claim 39, drawn to a bispecific binding composition comprising an antigen-binding composition comprising an **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 4** and another **antibody that binds specifically to a specific tumor antigen**, classified in Class 424, subclass 130.1.
8. Claim 39, drawn to a bispecific binding composition comprising an antigen-binding composition comprising an **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 5** and another **antibody that binds specifically to a specific tumor antigen**, classified in Class 424, subclass 130.1.
9. Claim 39, drawn to a bispecific binding composition comprising an antigen-binding composition comprising an **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 6** and another **antibody that binds specifically to a specific tumor antigen**, classified in Class 424, subclass 130.1.
10. Claim 39, drawn to a bispecific binding composition comprising an antigen-binding composition comprising an **antibody or binding fragment thereof that binds**

specifically to SEQ ID NO: 7 and another antibody that binds specifically to a specific tumor antigen, classified in Class 424, subclass 130.1.

11. Claim 39, drawn to a bispecific binding composition comprising an antigen-binding composition comprising an **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 2 and another antibody that binds specifically to a specific viral antigen, classified in Class 424, subclass 130.1.**
12. Claim 39, drawn to a bispecific binding composition comprising an antigen-binding composition comprising an **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 4 and another antibody that binds specifically to a specific viral antigen, classified in Class 424, subclass 130.1.**
13. Claim 39, drawn to a bispecific binding composition comprising an antigen-binding composition comprising an **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 5 and another antibody that binds specifically to a specific viral antigen, classified in Class 424, subclass 130.1.**
14. Claim 39, drawn to a bispecific binding composition comprising an antigen-binding composition comprising an **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 6 and another antibody that binds specifically to a specific viral antigen, classified in Class 424, subclass 130.1.**
15. Claim 39, drawn to a bispecific binding composition comprising an antigen-binding composition comprising an **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 7 and another antibody that binds specifically to a specific viral antigen, classified in Class 424, subclass 130.1.**
16. Claim 39, drawn to a bispecific binding composition comprising an antigen-binding composition comprising an **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 2 and another antibody that binds specifically to a specific microorganism antigen, classified in Class 424, subclass 130.1.**

17. Claim 39, drawn to a bispecific binding composition comprising an antigen-binding composition comprising an **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 4** and another **antibody that binds specifically to a specific microorganism antigen**, classified in Class 424, subclass 130.1.
18. Claim 39, drawn to a bispecific binding composition comprising an antigen-binding composition comprising an **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 5** and another **antibody that binds specifically to a specific microorganism antigen**, classified in Class 424, subclass 130.1.
19. Claim 39, drawn to a bispecific binding composition comprising an antigen-binding composition comprising an **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 6** and another **antibody that binds specifically to a specific microorganism antigen**, classified in Class 424, subclass 130.1.
20. Claim 39, drawn to a bispecific binding composition comprising an antigen-binding composition comprising an **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 7** and another **antibody that binds specifically to a specific microorganism antigen**, classified in Class 424, subclass 130.1.
21. Claim 40, drawn to a method of detecting the presence of NK cells using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 2**, classified in Class 435, subclass 7.1.
22. Claim 40, drawn to a method of detecting the presence of NK cells using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 4**, classified in Class 435, subclass 7.1.
23. Claim 40, drawn to a method of detecting the presence of NK cells using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 5**, classified in Class 435, subclass 7.1.

24. Claim 40, drawn to a method of detecting the presence of NK cells using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 6**, classified in Class 435, subclass 7.1.
25. Claim 40, drawn to a method of detecting the presence of NK cells using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 7**, classified in Class 435, subclass 7.1.
26. Claims 43-44, drawn to a method for selective removal of NK cell using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 2**, classified in Class 435, subclass 7.1.
27. Claims 43-44, drawn to a method for selective removal of NK cell using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 4**, classified in Class 435, subclass 7.1.
28. Claims 43-44, drawn to a method for selective removal of NK cell using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 5**, classified in Class 435, subclass 7.1.
29. Claims 43-44, drawn to a method for selective removal of NK cell using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 6**, classified in Class 435, subclass 7.1.
30. Claims 43-44, drawn to a method for selective removal of NK cell using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 7**, classified in Class 435, subclass 7.1.
31. Claim 47, drawn to a method for stimulation of NK cytotoxicity comprising contacting said NK cells with **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 2**, classified in Class 435, subclass 7.24.

Art Unit: 1644

32. Claim 47, drawn to a method for stimulation of NK cytotoxicity comprising contacting said NK cells with **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 4**, classified in Class 435, subclass 7.24.
33. Claim 47, drawn to a method for stimulation of NK cytotoxicity comprising contacting said NK cells with **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 5**, classified in Class 435, subclass 7.24.
34. Claim 47, drawn to a method for stimulation of NK cytotoxicity comprising contacting said NK cells with **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 6**, classified in Class 435, subclass 7.24.
35. Claim 47, drawn to a method for stimulation of NK cytotoxicity comprising contacting said NK cells with **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 7**, classified in Class 435, subclass 7.24.
36. Claim 50, drawn to a method for inhibiting NK cytotoxicity comprising contacting said NK cells with **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 2**, classified in Class 435, subclass 7.24.
37. Claim 50, drawn to a method for inhibiting NK cytotoxicity comprising contacting said NK cells with **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 4**, classified in Class 435, subclass 7.24.
38. Claim 50, drawn to a method for inhibiting NK cytotoxicity comprising contacting said NK cells with **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 5**, classified in Class 435, subclass 7.24.
39. Claim 50, drawn to a method for inhibiting NK cytotoxicity comprising contacting said NK cells with **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 6**, classified in Class 435, subclass 7.24.

40. Claim 50, drawn to a method for inhibiting NK cytotoxicity comprising contacting said NK cells with **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 7**, classified in Class 435, subclass 7.24.
41. Claims 53-56, drawn to a pharmaceutical composition comprising an effective amount of the isolated NK cells obtained by the purification method by contacting the biological sample with an isolated **antibody that binds specifically to SEQ ID NO: 2, antibody fragment thereof, or stimulated with said antibody**, in associated with a pharmaceutical acceptable carrier, Classified in Class 424, subclass 173.1.
42. Claims 53-56, drawn to a pharmaceutical composition comprising an effective amount of the isolated NK cells obtained by the purification method by contacting the biological sample with an isolated **antibody that binds specifically to SEQ ID NO: 4, antibody fragment thereof, or stimulated with said antibody**, in associated with a pharmaceutical acceptable carrier, Classified in Class 424, subclass 173.1.
43. Claims 53-56, drawn to a pharmaceutical composition comprising an effective amount of the isolated NK cells obtained by the purification method by contacting the biological sample with an isolated **antibody that binds specifically to SEQ ID NO: 5, antibody fragment thereof, or stimulated with said antibody**, in associated with a pharmaceutical acceptable carrier, Classified in Class 424, subclass 173.1.
44. Claims 53-56, drawn to a pharmaceutical composition comprising an effective amount of the isolated NK cells obtained by the purification method by contacting the biological sample with an isolated **antibody that binds specifically to SEQ ID NO: 6, antibody fragment thereof, or stimulated with said antibody**, in associated with a pharmaceutical acceptable carrier, Classified in Class 424, subclass 173.1.
45. Claim 58, drawn to a method for grafting enhancement and/or Graft versus Host (GvH) inhibition using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 2**, classified in Class 424, subclass 130.1.

Art Unit: 1644

46. Claim 58, drawn to a method for grafting enhancement and/or Graft versus Host (GvH) inhibition using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 4**, classified in Class 424, subclass 130.1.
47. Claim 58, drawn to a method for grafting enhancement and/or Graft versus Host (GvH) inhibition using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 5**, classified in Class 424, subclass 130.1.
48. Claim 58, drawn to a method for grafting enhancement and/or Graft versus Host (GvH) inhibition using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 6**, classified in Class 424, subclass 130.1.
49. Claim 58, drawn to a method for grafting enhancement and/or Graft versus Host (GvH) inhibition using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 7**, classified in Class 424, subclass 130.1.
50. Claim 58, drawn to a method for GvT stimulation using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 2**, classified in Class 424, subclass 130.1.
51. Claim 58, drawn to a method for GvT stimulation using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 4**, classified in Class 424, subclass 130.1.
52. Claim 58, drawn to a method for GvT stimulation using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 5**, classified in Class 424, subclass 130.1.
53. Claim 58, drawn to a method for GvT stimulation using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 6**, classified in Class 424, subclass 130.1.

Art Unit: 1644

- 54. Claim 58, drawn to a method for GvT stimulation using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 7**, classified in Class 424, subclass 130.1.
- 55. Claims 58-59, drawn to a method for preventing, palliation, and therapy of a tumor using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 2**, classified in Class 424, subclass 130.1.
- 56. Claims 58-59, drawn to a method for preventing, palliation, and therapy of a tumor using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 4**, classified in Class 424, subclass 130.1.
- 57. Claims 58-59, drawn to a method for preventing, palliation, and therapy of a tumor using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 5**, classified in Class 424, subclass 130.1.
- 58. Claims 58-59, drawn to a method for preventing, palliation, and therapy of a tumor using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 6**, classified in Class 424, subclass 130.1.
- 59. Claims 58-59, drawn to a method for preventing, palliation, and therapy of a tumor using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 7**, classified in Class 424, subclass 130.1.
- 60. Claim 58, drawn to a method for preventing, palliation, and therapy of microorganism infection using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 2**, classified in Class 424, subclass 130.1.
- 61. Claim 58, drawn to a method for preventing, palliation, and therapy of microorganism infection using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 4**, classified in Class 424, subclass 130.1.

62. Claim 58, drawn to a method for preventing, palliation, and therapy of microorganism infection using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 5**, classified in Class 424, subclass 130.1.
63. Claim 58, drawn to a method for preventing, palliation, and therapy of microorganism infection using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 6**, classified in Class 424, subclass 130.1.
64. Claim 58, drawn to a method for preventing, palliation, and therapy of microorganism infection using **antibody or binding fragment thereof that binds specifically to SEQ ID NO: 7**, classified in Class 424, subclass 130.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups 1-20 and 41-44 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the products as claimed differ with respect to their structure, binding specificity and physiochemical properties. Further, a prior art search also requires a literature search. It is a burden for the examiner to search more than one invention. Therefore, they are patentably distinct.

Inventions of Groups 21-40 and 45-64 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of treating different diseases using distinct product versus the method of detecting using distinct product differ with their respect to their process steps and endpoints. Therefore, they are patentably distinct.

Inventions of Groups (1-20 and 41-44) and Groups (21-60 and 45-64) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products as

Art Unit: 1644

claimed can be used in materially different process such as binding assays. Therefore, they are patentably distinct.

4. Because these inventions are distinct for the reasons given above and the searches are not co-extensive, restriction for examination purposes as indicated is proper.
5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.
7. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

October 6, 2003


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600